UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte SAUMIL N. MERCHANT and JOSEPH B. NADOL, JR.

Appeal No. 2005-0881
Application No. 09/625,644

HEARD: June 8, 2005

Before FRANKFORT, MCQUADE, and BAHR, Administrative Patent Judges.

FRANKFORT, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal from the examiner's final rejection of claims 1 through 26, all of the claims pending in the application.

Appellants' invention relates to a gas-filled balloon implant for implantation in a middle ear chamber and to a method of treating middle ear hearing loss using such a balloon-type implant. As can be seen, for example, in Figure 3 of the application, the

invention provides a gas-filled balloon (26) adapted to be surgically placed in the middle ear chamber (14) with at least a portion of the balloon in contact with the eardrum (12). Because the balloon membrane is pliant, and because the enclosed gas is relatively transparent to sound waves, the balloon (26) presents a relatively low acoustic impedance to the eardrum. As a result, the eardrum is almost as free to vibrate in response to incident sound waves as it would have been had the middle ear chamber been filled with air. As further explained on page 7 of the specification,

> [t]he acoustic impedance of the balloon 26 is measured in terms of its "equivalent volume." For a fixed temperature and pressure, the equivalent volume is defined as that volume of air whose acoustic impedance equals that of the balloon 26. The equivalent volume of the balloon 26 depends on the volume of the gas within the balloon 26, the choice of gas, the stiffness of the material comprising the balloon membrane 26a, the thickness of the membrane 26a, and the construction of the membrane 26a. Throughout this specification, the equivalent volume is expressed in terms of a percentage of the balloon's actual volume.
>
> [t]he balloon 26 is functionally equivalent to an air bubble having a size equal to the balloon's equivalent volume. As the equivalent volume of a balloon increases, its acoustic impedance decreases, and hence its compressibility increases. Accordingly, an increase in the equivalent volume of the balloon 26 increases its effectiveness as an implant for ameliorating conductive hearing loss.
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> [t]he equivalent volume of the balloon 26 is preferably greater than or equal to approximately 70% of its actual volume.

Independent claims 1, 21 and 22 are representative of the subject matter on appeal and a copy of those claims can be found in the Appendix to appellants' brief.

The prior art references relied upon by the examiner in rejecting the appealed claims are:

Nadol, Jr. (Nadol '430)	5,356,430	Oct. 18, 1994
Nadol, Jr. (Nadol '433)	5,480,433	Jan. 2, 1996

Claims 1, 3 through 20 and 22 through 26 stand rejected under 35 U.S.C. § 102(b) as being anticipated by either Nadol '430 or Nadol '433.

Claims 2 and 21 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over either Nadol '430 or Nadol '433.[1]

Rather than attempt to reiterate the examiner's full commentary with regard to the above-noted rejections and the conflicting viewpoints advanced by the examiner and appellants regarding those rejections, we make reference to the examiner's answer

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[1]As a result of the examiner's entry of the amendment filed January 28, 2003, the rejection of claim 2 under 35 U.S.C. § 112, second paragraph, set forth on page 2 of the final rejection has been overcome. Similarly, the examiner's approval of the terminal disclaimer filed October 28, 2002 has apparently overcome the double patenting rejection set forth on page 4 of the final rejection, since such rejection was not repeated in the examiner's answer.

(mailed August 12, 2004) for the reasoning in support of the rejections, and to appellants' brief (filed July 16, 2004) and reply brief (filed October 8, 2004) for the arguments thereagainst.

OPINION

Prior to our treatment of the examiner's rejections on appeal, we note that on page 4 of the brief appellants have indicated, under the heading "GROUPING OF CLAIMS," that claims 1 and 3 through 21 stand or fall together, that dependent claim 2 stands or falls on its own, and that claims 22 through 26 stand or fall together. Accordingly, in our discussions below we will focus on claims 1, 2 and 22, deciding the issues on appeal on the basis of those claims alone. As dictated by appellants, claims 3 through 21 will stand or fall together with claim 1, claim 2 will stand or fall on its own merits and claims 23 through 26 will stand or fall with claim 22.

In reaching our decision in this appeal, we have given careful consideration to appellants' specification and claims, to the applied prior art references, to the declaration filed by Mr. Nadol on January 28, 2003 and to the respective positions articulated by appellants and the examiner. As a consequence of our review, we have made the determinations which follow.

Looking first at the examiner's rejection of claims 1, 3 through 20 and 22 through 26 under 35 U.S.C. § 102(b) as being anticipated by either Nadol '430 or Nadol '433, we note that these patents both disclose a gas-filled balloon implant for implantation in a middle ear chamber for treatment of conductive hearing loss caused by otitis media and related ailments of the middle ear, and a method of treating middle ear hearing loss using such a balloon-type implant. The balloon implant is sized and configured to fit within the middle ear chamber and is formed of a thin pliant membrane filled with a gas or gas mixture. As noted in column 1, lines 35-37, it is an object of the invention in the Nadol patents "to provide an acoustic coupling or impedance match between the outer and inner ear." To that end, the synthetic bubble or balloon implant is positioned between the eardrum and the round window in the hypotympanic compartment of the middle ear (col. 1, lines 40-44) so as to displace fluid therebetween, thereby providing a reservoir of gas in a compressible form located proximate to the round window so that the round window is assured a degree of compliance comparable to that of a normal ear (col. 2, lines 51-58).

Claim 1 on appeal is directed to an implant for implantation in a middle ear chamber, wherein the implant comprises a pliant membrane formed into a balloon that is configured to fit within said middle-ear chamber and to contact an eardrum. Claim 1 goes on to recite that the balloon has "an equivalent volume selected to permit said

eardrum to respond to incident acoustic waves to an extent that permits the perception of sound." Given the structure and function of the balloon implants described in the Nadol patents as noted above, it is the examiner's position that they will inherently have an acoustic impedance and an "equivalent volume," and that once implanted in the middle ear chamber the balloon implants will permit the eardrum to respond to incident acoustic waves to an extent that permits the perception of some level of sound.

We agree with the examiner. Although the applied Nadol patents do not expressly discuss a balloon implant having an "equivalent volume," it is beyond question that balloon structures constructed in the manner described in the Nadol patents will have an "equivalent volume" and that those balloon structures when used in the manner described in the Nadol patents will generally be functionally equivalent to an air bubble having a size equal to the balloon's equivalent volume. Moreover, once implanted in the middle ear chamber, the balloon implants of the Nadol patents will clearly permit the eardrum to respond to incident acoustic waves to an extent that permits "the perception of sound," i.e., the perception of some level of sound, even if that level of sound must be very loud. Like the examiner, we note that claim 1 on appeal does not require that the balloon implant therein significantly increase acoustic transmission between the eardrum and the middle ear, or that it must significantly enhance a patient's perception of sound beyond that which may be possible when fluid

is present in the middle ear chamber. The balloon implant need only be constructed so as to permit the eardrum to respond to incident acoustic waves to an extent that permits the perception of some level of sound. Thus, both Mr. Nadol's declaration asserting that the balloons of the Nadol patents "did not significantly enhance acoustic transmission between the eardrum and the middle ear" and appellants' arguments based thereon in the brief are unpersuasive because they are not commensurate in scope with the broad recitations in claim 1. Likewise, appellants' genus/species argument in the reply brief is unavailing given the broad scope of claim 1 on appeal.

In accordance with the foregoing, we will sustain the examiner's rejection of independent claim 1 under 35 U.S.C. § 102(b) as being anticipated by Nadol '430 and Nadol '433. Given appellants' grouping of the claims noted above, it follows that claims 3 through 21 will fall with claim 1, and that the examiner's rejection of claims 3 through 20 under 35 U.S.C. § 102(b) and of claim 21 under 35 U.S.C. § 103(a) will also be sustained.

As for the examiner's rejection of claim 2[2] under 35 U.S.C. § 103(a) based on either Nadol '430 or Nadol '433, we share appellants' view that the examiner has

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[2]A correct copy of claim 2, reflecting the changes made in the amendment filed January 28, 2003, appears on page 2 of appellants' reply brief.

provided no reasonable evidential basis to support the statement on page 4 of the answer that for each model of balloon in the Nadol patents "the equivalent volume is at least 70% of the physical volume of the balloon." Contrary to the examiner's apparent belief, the equivalent volume of a balloon implant depends on many factors other than the fill level and type of gas contained in the balloon. See, for example, page 7, lines 14-17, of appellants' specification. For that reason, we will not sustain the examiner's rejection of claim 2 under 35 U.S.C. § 103(a).

As for the examiner's rejection of method claims 22 through 26 under 35 U.S.C. § 102(b) as being anticipated by either Nadol '430 or Nadol '433, we note that appellants' arguments in the brief and reply brief concerning these claims are the same as those we have found to be unpersuasive with regard to claim 1 above. We find those same arguments equally unpersuasive here, since the examiner has, in our view, correctly found that balloon implants like those described in the Nadol patents will inherently have an acoustic impedance and an "equivalent volume," and that once implanted in the middle ear chamber will permit the eardrum to respond to incident acoustic waves to an extent that permits the perception of some level of sound. Thus, the examiner's rejection of claims 22 through 26 under 35 U.S.C. § 102(b) will also be sustained.

To summarize: the rejection of claims 1, 3 through 20 and 22 through 26 under 35 U.S.C. § 102(b) and of claim 21 under 35 U.S.C. § 103(a) as posited by the examiner have been sustained. The rejection of claim 2 under 35 U.S.C. § 103(a) has not been sustained. Thus, the decision of the examiner is affirmed-in-part.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED-IN-PART

CHARLES E. FRANKFORT
Administrative Patent Judge

JOHN P. MCQUADE
Administrative Patent Judge

JENNIFER D. BAHR
Administrative Patent Judge

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